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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/273,230	03/18/1999	JEFFREY L. CLELAND	P0998D1	6833

7590 06/30/2004

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/30/2004

[Handwritten signature] 19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/273,230

Applicant(s)

CLELAND ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42 and 44-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/19/99, 7 & 3

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Re: Cleland *et al*
Priority Date: 27 July 1995

1. The amendment filed 11/26/2002 is acknowledged and entered into the record. Accordingly, claim 49 is canceled without prejudice or disclaimer.
2. Claims 42, and 44-48 are pending and examined on the record.

Information Disclosure Statement

3. The Information Disclosure Statement filed 7/14/1999, 12/27/2000, and 2/28/2001 are acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 103

4. The rejection of claims 42 and 44-48 under 35 USC 103(a) as being obvious over Hudziak *et al* (US Patent 5,770,195, herein referred to as `195)) in view of Hudziak *et al* (US Patent 5,720,954, herein referred to as `954) and Burton *et al* (Am J vet Res 1981 Feb;42(20):308-310) are maintained for the reasons of record. The claims are drawn to a method of administering a therapeutic amount of a formulation comprising an anti-Her2 antibody subcutaneously in a dose range of about 50mg/ml to 400 mg/ml. Applicant further argues that the prior art fails to disclose a method of subcutaneous administration. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable

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expectation of success. In *re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the prior art of Hudziak *et al* ('195) teaches the administration of an anti-HER2 antibody by other routes of administration, such as IV (see col. 11, lines 50-51). Therefore given the fact that Hudziak *et al* ('195) has already taught that the IV administration of an anti-HER2 antibody was effective in the treatment of a disease in a subject over-expressing the HER-2 antigen, there would be reasonable expectation of success for one of ordinary skill in the art to use subcutaneous administration of an antibody because the optimization of administration routes is clearly within the purview of the skilled artisan. Furthermore, it was also suggested by Hudziak *et al* ('195) to optimize the administration means (see col. 7, lines 38-42). Routes of administration alone does not breath any patentable weight into the claims unless the means of administration can be shown to be a critical aspect which provides some unexpected result over what has already been taught in the prior art.

With regard to the dose ranges, it has be held that differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In *re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the instant case, applicant has not presented any evidence or arguments to suggest that the higher dose ranges provide any significant improvement or unexpected results over the dose ranges taught in the prior art of Hudziak *et al*. Moreover, a *prima facie* case of obviousness

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exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Because the applicant has not presented any arguments or evidence that the claimed dose ranges of 50mg/ml – 400 mg/ml provide any significant different or unexpected result over the prior art, one of skill in the could easily increase the dosage through routine experimentation to arrive at the higher dose ranges, and therefore the disclosed ranges taught by the prior art are considered “close enough” to the claimed ranges.

Therefore, given the reasons set forth above, the rejection under 35 USC 103(a) is maintained.

Conclusion

5. **No claim is allowed.**

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
June 15, 2004


GARY NICKOL
PRIMARY EXAMINER